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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,596	03/18/2004	Michael Lange	905.020US2	9548

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EXAMINER

CHANG, CHING

ART UNIT PAPER NUMBER

3748

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,596

Applicant(s)

LANGE ET AL.

Examiner

Ching Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed on November 17, 2004.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1(a). ***Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Lange et al. (U.S. Patent 6,712,789).***

Although the claims are not identical, they are not patentably distinct from each other because the claim of the instant application are substantially the same as that claimed in the US Patent '789; however, the scope of claim 1 in the instant application lacking the limitations of separable to the sheath, the sheath including at least one tab

extending away from a longitudinal axis of the sheath, and sliding to a movable valve assembly, is broader than that of the claim 1 in US Patent '789.

1(b). *Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of Lange et al. (U.S. Patent 6,712,789).*

Although the claims are not identical, they are not patentably distinct from each other because the claim of the instant application are substantially the same as that claimed in the US Patent '789; however, the scope of claim 1 in the instant application lacking the limitations of separable to the sheath, a membrane, and sliding to a movable valve assembly, is broader than that of the claim 12 in US Patent '789.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. ***Claims 1, 9, and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al. (US Patent 5,755,693).***

Walker discloses an introducing apparatus (10) comprising: a tubular sheath (18) having an external diameter, the sheath having a sheath passage (24) including an internal diameter sized to receive a medical instrument (12) therethrough, the sheath extending from a sheath distal end to a sheath proximal end; a movable valve assembly (64, 64a) including a valve, the movable valve assembly movably coupled proximal to the sheath, the movable valve assembly movable from a first position (See Figs. 12 and 15) to a second position (other than the first position shown in Figs. 12 and 15) along a portion (28) of the introducing apparatus, in the first position the valve is disposed through the longitudinal axis of the sheath, in the second position the valve is disposed away from the longitudinal axis of the sheath, the movable valve assembly movable from the second position to the first position along (a portion (28) of) the introducing apparatus while the medical instrument is disposed (See Fig. 15) through the sheath passage along (the arrow shown in Fig. 5) at least the sheath proximal end; the movable valve defined in part by a movable valve longitudinal axis (perpendicular to the longitudinal axis of the sheath; also perpendicular to the arrow shown in Fig. 15); the movable valve assembly moves from a second position to a first position along the movable valve longitudinal axis (perpendicular to the longitudinal axis of the sheath; also perpendicular to the arrow shown in Fig. 15); wherein the movable valve assembly having an open end (76) substantially aligned with the movable valve longitudinal axis, the open end traveling over at least a portion of the sheath passage when the movable

valve assembly moves from the second position to the first position, and the valve disposed within at least a portion of the open end; wherein the valve comprises a membrane (30F), wherein the membrane has a slit (74) therein, wherein the slit is substantially parallel with the movable valve longitudinal axis, wherein the at least one tab (56, 58) is defined in part by a tab longitudinal axis, wherein the movable valve assembly includes a valve support member (70, 68, 66) coupled with a seal (30F), and the valve support member includes at least one arm (66, 68) at least partially encompassing the at least one tab.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. ***Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of Pohndorf et al. (US Patent 5,441,504).***

Walker discloses the invention, however, fails to disclose a dilator being used.

The patent to Pohndorf on the other hand, teaches that it is conventional in the art of a splittable lead introducer, to utilize a dilator (66) with an introducer (60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the dilator as taught by Pohndorf in the Walker device, since the use thereof would provide an improved introducer with a feature of an easier movement of a medical instrument therethrough.

6. *Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of West (US Patent 6,322,541).*

Walker discloses the invention, however, fails to disclose a side port assembly being coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a side port assembly (19, 20) having a snap-fit or thread-connection to an introducer sheath (12) (See Col. 2, line 56 through Col. 3, line 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the side port assembly as taught by West in the Walker device, since the use thereof would provide an improved introducer with an attachable side port for a flush or injection of other fluid in a vascular access system.

7. *Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US Patent 5,755,693) in view of West et al. (US Patent No. 6,322,541).*

Walker discloses an introducing apparatus comprising: an elongate tubular sheath (18) having an external diameter, the sheath having a bore (24) including an internal diameter sized to receive a cannula (12; or the like) therethrough, the sheath

comprising a separable sheath (through 56, 58, and 18); the sheath extending from a distal end to a proximal end; the sheath including at least one tab (56, 58) extending away from a longitudinal axis of the sheath; and a movable valve assembly (64, 64a) movably coupled relative to the at least one tab, the moveable valve assembly adapted to move from a first position (See Fig. 12 and 15) to a second position (other than the first position, along 28), in the first position the movable valve assembly disposed through the longitudinal axis of the sheath, in the second position the movable valve assembly disposed away from the longitudinal axis of the sheath.

Walker discloses the invention, however, fails to disclose a side port assembly being coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a side port assembly (19, 20), with a snap-fit connection or thread-connection to an introducer sheath (12) (see Col. 2, line 56 through Col. 3, line 8) having a dilator (14) therethrough.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the side port assembly with a snap-fit connection or thread-connection as taught by West in the Walker device, since the use thereof would provide an improved introducer with an attachable side port for a flush or injection of other fluid in a vascular access system.

8. ***Claims 2-7, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (as applied to claims 1 and 10 above) in view of Pohndorf et al. (US Patent 5,441,504).***

Walker discloses the invention, however, fails to disclose the movable valve assembly being slidable along the tab longitudinal axis.

The patent to Pohndorf on the other hand, teaches that it is conventional in the art of a splittable lead introducer, to utilize an introducer (60) with a dilator (66) therethrough and have a movable valve assembly (70) slidable along a tab longitudinal axis (72, 78).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the movable valve assembly with the slidable mechanism as taught by Pohndorf in the Walker device, since the use thereof would provide an improved introducer with an easier slidable, and movable valve assembly coupled with a seal to operate.

9. ***Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (as applied to claim 1) in view of West et al. (US Patent 6,322,541).***

Walker discloses the invention, however, fails to disclose a releasable side port being used.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a releasable side port assembly (19, 20) being used with a vascular access system (10). (See Col. 2, line 46 through Col. 3, line 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the releasable side port as taught by West in the Walker device, since the use thereof would provide an improved introducer with an attachable side port for a flush or injection of other fluid in a vascular access system.

Response to Arguments

10. Applicant's arguments filed on November 27, 2004 have been fully considered but they are not persuasive.

More specifically, regarding the Attorney's contentions to claims 1, and 10 "According to the Office Action, Walker discloses "the movable valve assembly movable (-- moves --) from the second position to the first position along the movable valve longitudinal axis," Page 5, Office Action, however no support is provided in the Office Action where this can be found. Furthermore, the Office Action states West (-- Walker --) discloses "the movable valve assembly movable from the second position to the first position along the introducing apparatus while the medical instrument is disposed (See Fig. 15) through the sheath passage." Page 5, Office Action Applicant respectfully traverses. No movement of the device supporting such an assertion can be found illustrated in Figure 15. " (See Page 7, Attorney's Remarks), and "For instance, Applicant cannot find in Walker a "movable valve assembly.....the medical instrument is disposed through the sheath passage" as recited in claim 1, and from which claims 2 - 8 depend. Furthermore, Applicant cannot find in Walker a "movable

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valve assembly moves from a second position to a first position along the movable valve longitudinal axis,the valve is disposed away from the longitudinal axis of the sheath" as recited in claim 10, from which claims 14 - 16 depend." (See Page 8, Attorney's Remarks), the Examiner disagrees. As a matter of fact, the Walker reference does teach " the movable valve assembly (64, 64a) moves from a second position (other than the first position shown in Figs. 12 and 15) to a first position (See Figs. 12 and 15) along the movable valve longitudinal axis (perpendicular to the longitudinal axis of the sheath; also perpendicular to the arrow shown in Fig. 15) ", " the movable valve assembly movable from the second position to the first position along (a portion (28) of) the introducing apparatus while the medical instrument is disposed (See Fig. 15) through the sheath passage along (the arrow shown in Fig. 5) at least the sheath proximal end ", and " in the first position the valve is disposed through the longitudinal axis of the sheath (18), in the second position the valve is disposed away from the longitudinal axis of the sheath ".

In addition, in response to applicant's argument that " the Office Action fails to establish a *prima facie* of obvious because there is no *objective* motivation to combine the references" (See Page 8, Attorney's Remarks), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed.

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Cir. 1992). Additionally, See *Ex Parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1896), " PREDICTABILITY IS DETERMINED AT THE TIME THE INVENTION WAS MADE ". Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. (See MPEP 2143.02).

Furthermore, regarding the Attorney's contentions on claims 17-22, " Claims 17-22 were rejected under 35 USC § 103(a) as being unpatentable over Walker et al....in view of West et al. Applicant respectfully traverses the rejection and submits that the Office Action fails to establish a prima facie case of obviousness, because all of the elements cannot be found in the cited reference. For instance, Applicant cannot find in the cited references "a side port assembly coupled with the sheath with the coupling, and the side port assembly includes one or more features allowing for the side port to be released from the sheath without damage or separation of the sheath or the side port" as recited in claim 17, from which claims 18 - 22 depend. ", and " While West states that "the hub 22 and the end cap 24 include a means for compressive connection there between, such as a snap-fit connection or a threaded connection." West, Col. 3, Lines 4 - 7, Applicant cannot find any such teaching for the side port assembly 19, 20. " (See Page 9, Attorney's Remarks), the Examiner disagrees. As a matter of fact, the West teaches " The hub of the hemostasis assembly 18 may include a side port 19 for connection to a flush or injection tube subassembly 20.....to the dilator 14 (See Col. 2, line 56 through line 63), and " the hemostasis valve assembly 18 include a hub 22, a cap24 and a gasket 26 disposed therebetween. The side port 19 of the hub 22 is not

illustrated. Similarly, although not illustrated for purpose of simplicity and clarity, the hub and the end cap 24 include a means for compressive connection therebetween, such as a snap-fit connection or a threaded connection, ***both of which are well-known in the art.*** " (See Col. 2, line 67 through Col. 3, line 8). Therefore, the Examiner deems that it would have been obvious to one having ordinary skill in the art at the time the invention was made, the combination of Walker reference and West reference would provide an improved introducer with an attachable side port for a flush or injection of other fluid in a vascular access system.

Furthermore, regarding the Attorney's contention to the rejection of claims 2-8, and 14-16, " Notwithstanding that the references fail to establish all of the elements of the claims, Applicant submits the Office Action fails to establish a prima facie of obviousness, because there is no objective motivation to combine the references. " (See Page 8, Attorney's Remarks), the Examiner disagrees. As a matter of fact, in the aforementioned teachings in Walker reference and West reference, the Examiner deems that it would have been obvious to one having ordinary skill in the art at the time the invention was made, the combination of Walker reference, West reference, and Pohndorf reference would provide an improved introducer with an easier operable and slidable valve assembly, and an attachable side port for a flush or injection of other fluid in a vascular access system.

Conclusion

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ching Chang whose telephone number is (571)272-4857. The examiner can normally be reached on M-Th, 7:00 AM -5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Denion can be reached on (571)272-4859. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

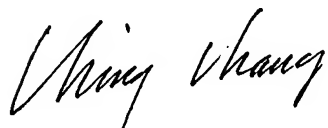
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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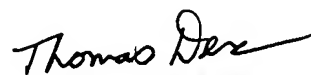
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Patent Examiner



Ching Chang



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